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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,197	01/12/2001	Pedro Aloise	BIO76701	2671

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EXAMINER
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SAYALA, CHRAYA D

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/760,197

Applicant(s)

ALOISE ET AL.

Examiner

C. SAYALA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new limitation "used as a media and having a substantially neutral pH" could not be found in the specification as originally filed. If applicant can point out where such terminology occurs in the specification, as originally filed, this rejection will be withdrawn.

The specification does not provide sufficient evidence to persons skilled in the art that the specification as filed contemplated the above limitations now claimed. See MPEP 2163. The standard for evaluating new matter in the claims is not whether the subject matter would be obvious to one skilled in the art from the specification as originally filed. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the

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written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). See MPEP 2163.02.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/34498 and Stone et.al. (J. Sci. Food Agric. Vol 35, pp 513-519, 1984) in view of EP 0321004 and Nielsen et al. (US Patent 5989600).

'498 teaches mixing krill hydrolysate with soy, canola and other plant protein along with wheat bran, being brought to a desired temperature of about 45<sup>0</sup> C, and

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holding it for about 1 hour at this temperature. At page 19, lines 9+, the reference states that the enzymes in krill carry out a *limited hydrolysis* of soy, canola and other plant proteins. The phytic acid and levels of acid and base are measured. Wheat bran is used to provide phytase. The patent teaches that the blend can be maintained to an extended period of time, 4 hours or even longer. The krill hydrolysate product is evaporated and then mixed with and co-dried with a dry carrier, such as canola meal, oil seed meal, which renders obvious the soybean meal and other vegetable meals. The advantages are given at p. 20; see page 19 and page 22, lines 5-10.

'498 also teaches using formic acid to stabilize the hydrolyzed marine protein. It does not teach adding acid to stabilize hydrolyzed feed materials from vegetable/oil seed protein. However, it would have been obvious to use the same acid to stabilize such since the krill hydrolysate used is the same.

The patent does not teach the use of a phytase enzyme instead of wheat bran, and does not teach the use of a pH between 5-5.5.

Stone et. al teach acid-stabilized blend of fish silage, wheat bran and canola meal to make a feed-stuff. The pH is maintained at 4.0 and the final blend is dried. Stone et al. teach stabilizing the product with acid at page 518, second paragraph. The use of phytase enzyme is not taught and neither is the pH the same as claimed herein.

EP 0321004 teaches the uses of phytase *either* from wheat or from microbial source. It also teaches using a combination of enzymes that possess plant degrading

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properties. See claims 1-4. See claim 6, wherein the process teaches drying the hydrolyzed product.

Nielsen et al. also teach using a combination of enzymes such as phytase and proteolytic enzymes for dephosphorylating the same cereals as claimed herein and shown by '498, see col. 1, lines 53-55; col. 3, lines 40-65. The pH used is between 4-7. The temperatures are from 35-65°C. See col. 3, lines 10-25.

It would have been obvious to combine krill hydrolyzate, canola meal, phytase or other film-degrading enzymes used in EP '004 or Nielsen et. al., to prepare a feedstuff as taught by WO '498 and drying the hydrolyzed product as shown in the secondary reference and co-drying with other feed ingredients as shown by '498. Note that all patents are drawn to hydrolyzing feed materials to make animal feedstuff by using phytase enzyme. To substitute the wheat bran of the primary references (Stone et al., WO '498) with phytase would have been an obvious substitution since these references teach that wheat bran is used as a phytase source and both Nielsen et. al. and EP '004 use the phytase enzyme itself. The temperatures shown by these references are close to or encompass these parameters claimed herein and to optimize such, based on the known phytase activity around pH 5 to 5.5 would have been an obvious expedient. It is well known that each enzyme has optimal activity at a specific temperature and pH, as also phytase. And therefore, it is immaterial if the krill hydrolysate is a neutral media or not, because it would have been obvious to one of ordinary skill in the art at the time to adjust such conditions anyway, to what would be optimal for phytase activity.

***Claim Rejections - 35 USC § 102/35 USC § 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 15 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO98/34498 or Stone et al.

The patents/references above teach the addition of enzymes such as phytase to hydrolyze the same feed materials as claimed herein. The flavors are in amounts 0-5% (see claim 1). The rejection is being made under both statutes because the Office is not equipped to make prior art products and compare them with those of applicant's claims and so the burden is being shifted to applicant to show that these product claims are distinguishable over prior art. Applicants' claim is written in product-by-process format and as such, it is the novelty of the instantly claimed product that need be established and not that of the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, 191 USPQ (CCPA 1976). When the prior art discloses a product that reasonably appears to be either identical with or only slightly different than the product claimed in this product-by-process claim, the burden is on the applicant to present evidence from which the Examiner could reasonably conclude that the claimed product differs in kind from those of prior art. In re Brown, 459 F2d 531, 173 USPQ 685 (CCPA

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1972); In re Fessman, 489 F2d 742, 180 USPQ 323 and 324 (CCPA 1974); In re Marosi, 710 F2d 799, 218 USPQ 195 (Fed Cir. 1983).

### ***Response to Arguments***

4. Applicant's arguments filed 3/11/2004 have been fully considered but they are not persuasive.

The rejection of claims in paragraph 1 (above), is being maintained. Applicant has stated that with respect to the limitation "used as media and having a substantially neutral pH", "there is no specific reference to the claim limitation", but it is "inherent" throughout.

Applicant refers to page 6, lines 4-5, where he states that because the specification here states "It is proposed to add a liquid hydrolyzate to canola meal or other grains used in feed material", then, from this it is clear that the hydrolyzate is used as liquid media. He further states that phytase is a liquid as well, but this addition is only in minute amounts, so that it does not contribute to the overall wetness of the slurry.

None of this is as clear as applicant states it is. For instance, nowhere in the specification is it ever stated that the hydrolysate is used as a media. In fact, the specification states that the liquid hydrolysate is added to canola meal or other grains "to transform enzymatically", the canola meal or other grains. The liquid hydrolysate is derived from krill. There is no disclosure in prior art as to its use other than as a liquid hydrolysate for its enzyme activity. See WO '498, which teaches that krill hydrolysate



provides *limited hydrolysis* of soy, canola and other plant proteins. Therefore, it is neither clear from applicant's disclosure as originally filed, nor from prior art that the liquid hydrolysate was used as a media in the instant application, nor is there any evidence to draw such a conclusion.

As for the limitation "substantially neutral pH", applicant has argued that at page 7, lines 6-7, the specification describes that the pH is "lowered to between 5.0-5.5...." and this implies that before being lowered, the pH must have been higher. Furthermore, applicant states that "lowered to between 5.0-5.5.." implies that "the pH of the hydrolysate and canola meal was in a substantially neutral range centered around the neutral value of 7". There is no basis to make this assumption nor does the specification provide any basis or support for this new limitation. There is no basis that "lowered to between 5.0-5.5" should be taken to imply that the pH before such lowering was at a "substantially neutral range, centered around the neutral value of 7". In fact, "lowered to between 5.0-5.5" can be construed to mean that the pH was lowered from pH 14 or anywhere from 14 to 5.5 or 5.0 or anywhere in between, not necessarily pH=7, or near about. Applicant has now chosen to interpret this as being "substantially neutral". There is no basis for this in the specification as originally filed. Applicant's assertion that the pH of the hydrolysate before mixing with the canola meal is between "6.8 and 7.0...." is not disclosed, not inherent and not substantiated by any evidence in prior art.

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Therefore, in absence of such disclosure at the time of filing, 1) the use of the liquid hydrolysate together with the cereal feed is to transform the cereal enzymatically and 2) lowering the pH does not imply that it was substantially neutral, before lowering.

At page 7 of his remarks, applicant has stated again, that WO '498 does not teach the phytase enzyme, but it teaches wheat bran. It is for this reason that the rejection is being made under 35 USC 103 and not under 102.

At page 19 of the reference, '498 states: *"Experiments conducted to date utilize the enzymes in krill to carry out a limited hydrolysis of soy, canola and other plant proteins"*.

And:

*"The use of wheat bran is necessary to provide phytase, an enzyme which is absent in canola meal and krill"*.

Such statements provide motivation to provide phytase, because of limited hydrolysis by the enzymes in krill.

In his arguments, with respect to the Stone et al. reference, applicant is in error. He states that "This is in contradistinction to the present invention which does not need acid stabilization...". Instant claim 1 recites: "stabilizing said mixture to prevent bacteria formation...". At page 7 of the specification, lines 11-13, the stabilization is described thus: *"The mixture was thereafter acidified using formic acid to give a pH of below 4.0 for stabilization"*.

Stone et al. teach using acid stabilization for their composition, which is similar, and obtaining a low pH. The instant claims do not recite any pH value for the acid

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stabilization and therefore the argument that the reference teaches a lower pH than 5.0 is irrelevant. The reference (page 518) states that:

*"Canola meal phytic acid is most soluble at pH 4.8 and is only slightly less soluble at pH 4.0. Phytase is most active at pH 5.0-5.5 but retains over 70% of its activity at pH 4.0. Although the pH necessary to obtain maximum storage life of the blends was lower than for optimum phytase activity, it appears that at pH 4.0 conditions are acceptable for preservation, proteolytic hydrolysis, and for phytase activity".*

Applicant's pointing out that the reference teaches fish silage not krill hydrolysate is also unpersuasive. Stone et al. teach using fish silage and phytase from wheat bran, to dephosphorylate canola meal and therefore, it is a reference that is drawn to the same inventive concept, given the fact that WO '498 discloses that the fish hydrolysate does not provide adequate enzymes, causing the addition of phytase in the form of wheat bran and, Stone et al teach the addition of fish silage *and wheat bran* for its phytase.

The examiner is aware that the EP patent and Neilsen do not teach the use of fish hydrolysates, but both patents are drawn to hydrolysis of vegetable proteins using phytase enzyme and have been applied for such teachings.

With regard to the 102/103 rejection, the reference compositions are the same: It contains a fish hydrolysate, cereal and phytase. Whether the phytase is from wheat bran or just an exogeneous enzyme, it is still phytase and therefore, the composition would be the same. Barring any evidence to the contrary, the product is being held as the same. Applicant's reference to the European application being favorably considered

over the same references cannot be used as the basis of establishing patentability in the US case. There is no rule or case law to justify such a position.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. SAYALA whose telephone number is 571-272-1405.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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